

# Becket Systems

An Independent Review Organization  
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## NOTICE OF INDEPENDENT REVIEW DECISION

### DATE OF REVIEW:

Mar/24/2010

### IRO CASE #:

### DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

L5-S1 Arthroplasty and 2 Days LOS - Lumbar

### DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:

M.D., Board Certified Orthopedic Surgeon  
Board Certified Spine Surgeon

### REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

☒ Upheld (Agree)

☐ Overturned (Disagree)

☐ Partially Overturned (Agree in part/Disagree in part)

### INFORMATION PROVIDED TO THE IRO FOR REVIEW

ODG Guidelines, Low Back Chapter

Adverse Determination Letters, 1/28/10, 3/1/10

Center for Diagnostics & Surgery 1/15/10

Center for Diagnostics & Surgery 9/11/06

nstitute 2/15/10, 1/4/10, 2/15/10, 5/9/07, 11/13/06, 9/15/06, 6/28/06, 5/19/06

DMC 10/13/08

Pain Care Center 12/3/09, 11/10/09

Specialty Group 5/21/09, 4/18/06

Spine & Scoliosis Institute 9/25/08, 10/28/08

CoPE 1/15/10

"Prospective Randomized Multicentered Food and Drug Administration Investigation to Advise Exemption Study of Lumbar Total Disc Replacement with Charite Artificial Disc Versus Lumbar Fusion, Five Year Followup," Guyer, McAfee, Banco, Bitan, Ceno, Guisler, Hockschuler, Holt, Genis, Nijad, Reagan, Tomlin, Howser, Long, Blumenthal, Spine Journal, 9/2009, pages 374-378)

### PATIENT CLINICAL HISTORY SUMMARY

This is an injured worker who, according to records, sustained an injury on xx/xx/xx. The injured worker complained of low back pain predominantly with some radiculopathy. There has been a diagnosis of internal disc disruption of L5/S1 on MRI scan and with provocative discography. There is noted to be unilateral facet hypertrophy at L5/S1 and bilateral

hypertrophy at L4/L5. There has been noted to be some instability at L5/S1 with retrolisthesis noted, although this does not appear to conform to AMA Guidelines for instability at this level. Current request is for an artificial disc at L5/S1.

**ANALYSIS AND EXPLANATION OF THE DECISION INCLUDING CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION**

The article from The Spine Journal 9, 2009, 374-386, provided by the treating physician, notes in its conclusion that “Results of this five-year perspective randomized multicenter study are consistent with the two-year reports of non-inferiority of Charite artificial disc versus A-lift with DA cage and iliac crest autograft. Point, no statistical significance was found in safety and clinical success outcomes between the group. This study represents the largest and longest randomized perspective multicentered arthroplasty trial performed to date.”

The conclusion of this article supports the statutorily mandated Official Disability Guidelines and Treatment Guidelines concerning the nonrecommendation for disc prosthesis in the lumbar spine, as the chapter in the Low Back section notes. There has been no documented superiority in artificial disc arthroplasty versus one-level lumbar fusion. It is for this reason that the previous adverse determination cannot be overturned. The reviewer finds that medical necessity does not exist for L5-S1 Arthroplasty and 2 Days LOS – Lumbar.

**A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION**

☐ ACOEM-AMERICA COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE

☐ AHCPR-AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES

☐ DWC-DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES

☐ EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN

☐ INTERQUAL CRITERIA

☒ MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS

☐ MERCY CENTER CONSENSUS CONFERENCE GUIDELINES

☐ MILLIMAN CARE GUIDELINES

☒ ODG-OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

☐ PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR

☐ TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS

☐ TEXAS TACADA GUIDELINES

☐ TMF SCREENING CRITERIA MANUAL

☐ PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)

☒ OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)

    (“Prospective Randomized Multicentered Food and Drug Administration Investigation to Advise Exemption Study of Lumbar Total Disc Replacement with Charite Artificial Disc Versus Lumbar Fusion, Five Year Followup,” Guyer, McAfee, Banco, Bitan, Ceno, Guisler, Hockschuler, Holt, Genis, Nijad, Reagan, Tomlin, Howser, Long, Blumenthal, Spine Journal, 9/2009, pages 374-378)